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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/014,087	01/27/1998	WENDA C. CARLYLE	1416.25US01	4103

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EXAMINER
PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 10/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	09/014,087	CARLYLE ET AL.	
	Examiner	Art Unit	
	Paul B. Prebilic	3738	

-- The MAILING DATE of this communication app ars on the cover sh et with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-11,14,15 and 21-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-11,14,15 and 21-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4-6, 9-11, 14, and 21-29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 8-11, 13, 15, and 34-40 of copending Application No. 09/186,810. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter of the copending claims is so similar to the present claimed subject matter that it read n it and is at least clearly obvious thereover.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The language "fully crosslinked" lacks original support in that it is not disclosed, or at least not explicitly disclosed. It would have to be shown that all crosslinkable sites where crosslinked. Since no organic reaction goes to absolute 100% completion, it is the unclear what degree of crosslinking constitutes full crosslinking.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

Claims 25 to 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The new language of fully crosslinked is considered to be unclear because it was not described with regard to what falls within the claim definition for fully crosslinked. Since no organic reactions go to 100% completion, it is the unclear what degree of crosslinking constitutes full crosslinking. At the minimum, the language "fully crosslinked" lacks antecedent basis from the specification.

The language "exogenous" is not understood with regard to the specification, which does not describe such. Furthermore, the language lacks antecedent basis from the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States..

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 25 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Cahalan (US 5,308,641), or alternatively, under 35 USC 103(a) as being unpatentable over Cahalan (US 5,308.641) alone wherein the human or animal tissue is used as the solid surface and the biomolecule is one of the growth factors listed on column 6, lines 14-18; see the whole document, especially the abstract, column 4, lines 20-43, and column 6, lines 8-28. It is noted that "fixed" and "crosslinked" are synonymous in the tissue graft implant art. Furthermore, light crosslinking may be "fully crosslinking" to the extent that this terminology is definite and described in the specification.

* Glutaraldehyde can be used; see Col. 4, l. 5 58–62.

Alternatively, if one considers Cahalan's implant only light and not fully crosslinked, than the claim language is not met. However, the Examiner posits that the claim language is at least obvious over Cahalan's implant since light crosslinking is only

preferred by Cahalan and Applicants have not shown some unexpected/unobvious result with full crosslinking.

Claims 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Bayne et al (EP 0476983), or alternatively, under 35 USC 103(a) as being unpatentable over Bayne et al alone wherein the fibrin coating is applied prior to or in addition to the VEGF II growth factors to the surface of the fixed umbilical cord vein; see the whole document, especially page 8, lines 14-26, and in particular, page 8, lines 20-23. The Examiner posits that the tubular supports coated with VEGF II include fixed umbilical cord vein, and thus, the claim language is fully met.

Alternatively, if one does not consider the tubular supports coated with VEGF II as including umbilical cord vein, than the claim language is not fully met. However, the Examiner posits that it would have been clearly obvious to use umbilical cord vein as the tubular support since it is used as an implant in another procedure it would bring the desired features of tissue properties to the implant site.

Claims 1-2, 4-5, 9-11, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bayne et al (EP 0476893) in view of Wadstrom (US 5,631,011). Bayne et al discloses an implant having a fibrin coating (a biologic adhesive as claimed), which is applied prior to the VEGF II growth factor (VEGF II is the polypeptide growth factor as claimed). The fixed umbilical cord vein of Bayne et al is the substrate for coating as claimed; see page 8, lines 14-26. However, the Bayne et al cord vein, although a crosslinked human or animal tissue, is not ~~clear~~ clearly either an allograft or xenograft as claimed. Nonetheless, it is the Examiner's position that it would have been

considered clearly obvious to an ordinary artisan to use an allograft or xenograft tissue for the cord vein of Bayne et al absent some showing of criticality therefor. Wadstrom is cited to show that fibrin is a common biologic tissue adhesive in the art, and thus, the fibrin coating of Bayne et al can be called and would function as a biologic adhesive as claimed.

Claims 6-8, 14, 15, 21-24, and 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bayne et al and Wadstrom as applied to claims 1-5, 9-11, and 29 above, and further in view of Carpentier (US 4,648,881). Bayne et al fails to disclose uncrosslinked tissue, the heart valve form of the tissue, or the other tissue types as claimed. However, Carpentier teaches that all uncrosslinked and crosslinked forms of tissue, heart valve tissue forms and other types of tissue are all well known in the art; see the ~~entire document~~. Hence, it is the Examiner's position that it would have been obvious to use any of these materials as the substrate of Bayne et al for the applications contemplated by Carpentier. One would be motivated to form Bayne et al implants into other shapes in order to make ~~is~~ it useful in other sites and broaden its applicability.

Response to Arguments

Applicants' arguments filed August 19, 2002 have been fully considered but they are not persuasive.

In response to the traversal that the Examiner has fallen short in showing a lack of written description, the Examiner has reconsidered his position and withdrawn one

basis of the rejection. However, the rejection that "fully crosslinked" is not adequately described as been maintained because there is no basis for it in the specification.

As to the Section 112, second paragraph rejections, the Examiner maintains that at least there is no antecedent basis for these terms from the specification. They are considered indefinite because there have not been adequately defined. The Examiner agrees that literal support is not required, but Applicants have failed to point out where the terminology has inherent support.

In response to the traversal that dilute concentrations of crosslinking agent is preferred not light crosslinking, the Examiner that the two are directly connected by Cahalan. Cahalan states:

> "*Preferably, the crosslinking agent used to crosslink the polyalkylimine is applied in dilute solution and at a suitable pH to accomplish light crosslinking and to provide aldehyde functionality for the polyalkylimine surface that will allow biomolecules to readily bond to the spacer.*"

For this reason, the Examiner asserts that light crosslinking is merely a preference not a criticality as apparently held by the Applicants.

In response to the argument about full crosslinking, again the Examiner asserts that light crosslinking is merely a preference not a criticality. Furthermore, since full crosslinking has not been defined, the Examiner posits that even the light crosslinking reads on the claim language.

As to the traversal of the rejection under 35 USC 102(b) over Bayne et al, the Examiner asserts that VEGF II is coated on all the implants regardless of whether they have cells precoated thereon of not. As such, the fibrin adhesive is coated on the implant surface with or without a layer of cells thereon. The claim language does not

preclude a layer of cells thereon. Furthermore, since the VEGF II is disclosed as being applied to promote cell growth in vivo and is applied immediately prior to implantation, it would make the most logical sense to interpret the language as the Examiner has interpreted. That is that the VEGF II is applied last after the other components have been attached to the artificial vessel.

Next, Applicants traverse the Bayne et al in view of Wadstrom rejection by stating that fibrin monomers are an adhesive not the polymer thereof. The Examiner asserts that fibrin, by definition, is a polymer. It is formed by the reaction of fibrinogen and thrombin (Hawley's Condensed Chemical Dictionary 11th edition, page 520). There is no such thing as fibrin monomers. Furthermore, if fibrin is an adhesive for cells than it is an adhesive nonetheless. For this reason, the claim language is fully met in this regard.

In the traversal of the Carpentier modified Bayne rejection, Applicants argue that Carpentier does not teach the use of growth factors. The Examiner has pointed out how the use of growth factors is at least obvious in view of Bayne alone. Carpentier was not used to teach this concept so the traversal is a piecemeal analysis of the reference. Similarly, Wadstrom was not used to teach valved implants so this traversal constitutes a piecemeal analysis. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Since the secondary references were used to teach the use of other components with Bayne, it is not persuasive to traverse them on the basis of what Bayne et al discloses.

As to the motivation to combine Carpentier with Bayne, the Examiner has expanded the one provided in the rejection such that it is clear it has at least one motivation set forth.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9301.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.

Paul Prebilic
Primary Examiner
Art Unit 3738